भारतीय मानक
Indian Standard

IS 18429 : 2023

त्वचा जैल — विशिष्टि

Skin Gel — Specification

ICS 71.100.70

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October 2023 **Price Group 5**

Cosmetics Sectional Committee, PCD 19

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Cosmetics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

Gels are semisolid systems consisting of hydrophilic or hydrophobic base and varied viscosity. Gels have jelly like appearance and may be transparent, translucent or opaque systems meant for cosmetic application on skin. Gels are usually light weight and gets easily absorbed in skin.

A scheme for labelling environment friendly products known as ECO Mark (optional) has been introduced at the instance of the Ministry of Environment and Forests (MEF), Government of India. The ECO Mark is being administered by the *Bureau of Indian Standards Act*, 2016 as per the Resolution No. 71 dated 21 February 1991 and No. 768 dated 24 August 1992 published in the Gazette of the Government of India. For a product to be eligible for marking with ECO logo, it shall also carry the Standard Mark of BIS besides meeting additional environment friendly requirements. For this purpose, the Standard Mark of BIS would be a single mark being a combination of the BIS Standard Mark and the ECO logo. Requirements for the ECO friendliness will be additional, manufacturing units will be free to opt for Standard Mark alone also.

The composition of the Committee, responsible for the formulation of this standard is given in Annex D.

For the purpose of deciding whether a particular requirement of this standard is complied with,the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*)’.The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

SKIN GEL — SPECIFICATION

1 SCOPE

This standard prescribes the requirements and methods for sampling and test for skin gel, for its use as a cosmetics.

2 REFERENCES

The standards given below contain provisions, which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of these standards:

IS No.	*Title*
IS 2088 : 2023	Methods for determination of arsenic (*third revision*)
IS 3958 : 2021	Methods of sampling cosmetics (*second revision*)
IS 4011 : 2018	Methods of test for safety evaluation of cosmetics (*third revision*)
IS 4707	Classification of cosmetic raw materials and adjuncts:
(Part 1) : 2020	Colourants (*fourth revision*)
(Part 2) : 2017	List of raw materials generally not recognized as safe for use in cosmetics (*fourth revision*)
IS 14648 : 2011	Microbiological examination of cosmetics and cosmetic raw materials — Methods of test (*second revision*)
IS 16913 : 2018	Methods of test for cosmetics — Determination of heavy metals (arsenic, cadmium, lead and mercury) by atomic absorption spectrometry (AAS)
IS 17495 : 2021	Cosmetics — Analytical approach for screening and quantification methods for heavy metals in cosmetics

3 REQUIREMENTS

3.1 Description

Skin gels are jelly semisolid preparations. It could be in aqueous or non-aqueous base.

3.2 Unless specified otherwise, all the raw materials used in the manufacture of skin gel shall conform to the requirements prescribed in the relevant Indian Standards where these exist.

3.3 All ingredients of skin gel shall comply with the provisions of IS 4707 (Part 1) and IS 4707 (Part 2) subject to the provisions of *the Drugs and Cosmetics Act*, 1940 and rules framed thereunder.

3.4 For safety evaluation of novel ingredients used in the formation of skin gel, it shall comply to IS 4011.

3.5 The cosmetic product shall also comply with the requirements given in Table 1 when tested as prescribed in col (4) of table 1.

3.6 Additional Requirements for ECO Mark (Optional)

3.6.1 *General Requirements*

3.6.1.1 The product shall confirm to the requirements for quality, safety and performance given in **3.6.1.2** to **3.6.1.5**

3.6.1.2 All the ingredients that go into the formulation of cosmetics shall comply with the provisions of IS 4707 (Part 1) and IS 4707 (Part 2). The product shall also meet the specific requirements as given in the standard.

3.6.1.3 The product package shall display a list of key ingredients in descending order of quality present.

3.6.1.4 The product shall not be manufactured from any carcinogenic ingredients.

3.6.1.5 The manufacturer shall produce to BIS environmental consent clearance from the concerned State Pollution Control Board as per the provisions of *the Water* (*Prevention and Control of Pollution*) *Cess Act*, 1977 and *the Air (Prevention and Control Pollution) Act,* 1981 along with the authorization, if required under the *Environment (Protection) Act*, 1986 and the rules made thereunder, while applying for ECO Mark.

Additionally, provisions of *the Drugs and Cosmetics Act*, 1940 and the rules thereunder shall also be complied with.

4 PACKING AND MARKING

4.1 Packing

The material shall be packed in suitable well-closed containers.

4.2 Marking

The containers shall be legibly marked with the following information:

a) Name of the material;
b) Manufacturer's name and its recognized trade-mark, if any;
c) Net content;
d) Batch number;
e) Use before or expiry date as per statutory requirements;
f) List of ingredients as per statutory requirements; and
g) Any other information required by statutory authorities.

4.3 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

5 SAMPLING

5.1 Representative samples of the product shall be drawn as prescribed in IS 3958.

5.2 Test for all characteristics shall be carried out on the composite sample.

5.3 The product shall be taken to have confined to the specification if the composite sample passes all the tests.

6 QUALITY OF REAGENTS

Unless specified otherwise, pure chemicals and distilled water (*see* IS 1070) shall be employed in tests.

NOTE — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the result of analysis.

Table 1 Requirements for Skin Gel

(*Clause* 3.5)

Sl No.	**Characteristic**	**Requirement**	**Method of Test, Ref to**	
			Annex	**IS**
(1)	(2)	(3)	(4)	(5)
i)	*p*H at (27 ± 2) ºC	3.0 to 9.0	A	
ii)	Heavy metals (as lead), parts per million, *Max*[1)]	20	B	IS 16913
iii)	Arsenic (as As_2O_3), parts per million, *Max*[2)]	2	C	IS 16913 or IS 17495
iv)	Mercury, parts per million, *Max*	1	—	IS 16913 or IS 17495
v)	Microbial limit:	—	—	
	a) Total microbial count, CFU/g, *Max*	< 1 000 cfu	—	IS 14648
	b) Yeast and mould count, CFU/g, *Max*	< 100 cfu	—	
	c) *Pseudomonas aeruginosa*, per gram	Absent	—	
	d) *Escherichia coli*, per gram	Absent	—	
	e) Staphylococcus aureus, per gram	Absent	—	
	f) Candida albicans, per gram	Absent	—	

[1)] In the event of any dispute, Colorimetric method mentioned in Annex B would be treated as referee method.

[2)] In the event of any dispute, Colorimetric method mentioned in Annex C would be treated as referee method.

ANNEX A

[*Table* 1, *Sl No.* (i)]

DETERMINATION OF *p*H

A-1 APPARATUS

A *p*H metre, preferably equipped with a glass electrode.

A-2 PROCEDURE

Weigh accurately (5 ± 0.01) g of the sample in a 100 ml beaker, add 45 ml of water and disperse the skin gel in it. Determine the *p*H of the sample at (27 ± 2) ºC using the *p*H metre.

ANNEX B

[*Table* 1, *Sl No.* (ii)]

TEST FOR HEAVY METALS

B-1 OUTLINE OF THE METHOD

The colour produced with the hydrogen sulphide solution is matched against that obtained with the standard lead solution.

B-2 APPARATUS

B-3 REAGENTS

B-3.1 Dilute Hydrochloric Acid — approximately 5 N

B-3.2 Dilute Acetic Acid — approximately 1 N

B-3.3 Dilute Ammonium Hydroxide — approximately 5 N

B-3.4 Hydrogen Sulphide Solution — saturated

B-3.5 Standard Lead Solution

Dissolve 1.600 g of lead nitrate in water and make up the solution to 1 000 ml. Pipette out 10 ml of the solution and again to 1 000 ml with water. One millilitre of this solution contains 0.01mg of lead (as Pb).

B-4 PROCEDURE

Weigh about 2.000 g of material in a crucible and heat on a hot plate and then in a muffle furnace to ignite it at 600 ºC to constant mass. Add 3 ml of dilute hydrochloric acid, warm (wait till no more dissolution occurs) and make up the volume to 100 ml. Filter the solution. Transfer 25 ml of the filtrate into Nessler’s cylinder. In the second Nessler’s cylinder, add 2 ml of dilute acetic acid, 1 ml of standard lead solution and make up the volume with water to 25 ml.

Add 10 ml of hydrogen sulphide solution to each Nessler’s cylinder and make up the volume with water to 50 ml, mix and allow to stand for 10 min. Compare the colour produced in the two Nessler’s cylinders. Blank determination without samples are recommended to avoid errors arising out of reagents.

B-5 RESULTS

The sample may be taken to have passed the test, if the colour developed in the sample solution is less than that of standard solution.

ANNEX C

[*Table* 1, *Sl No.* (iii)]

DETERMINATION OF ARSENIC

C-1 OUTLINE OF THE METHOD

Arsenic present in a solution of the material is reduced to arsine, which is made to react with mercuric bromide paper. The stain produced is compared with standard stain.

C-2 REAGENTS

C-2.1 Mixed Acid

Dilute one volume of concentrated sulphuric acid with four volumes of water. Add 10 g of sodium chloride for each 100 ml of the solution.

C-2.2 Ferric Ammonium Sulphate Solution

Dissolve 64 g of ferric ammonium sulphate in water containing 10 ml of mixed acid and make up to 1 litre.

C-2.3 Concentrated Hydrochloric Acid — (*see* IS 265)

C-2.4 Stannous Chloride Solution

Dissolve 80 g of stannous chloride solution ($SnCl_2.2H_2O$) in 100 ml of water containing 5 ml of concentrated hydrochloric acid.

C-3 PROCEDURE

Carryout the test as prescribed in IS 2088, adding into the Gutzeit bottle, 2 ml of ferric ammonium sulphate solution, 0.5 ml of stannous chloride solution and 25 ml of sample solution as prepared in **B-4.**

For comparison, prepare stain using 0.001 mg of arsenic trioxide

ANNEX D

(*Foreword*)

COMMITTEE COMPOSITION

Cosmetics Sectional Committee, PCD 19

Organization	*Representative (s)*
Central Drugs Standard Control Organization, New Delhi	DR RAJEEV SINGH RAGHUVANSHI **(*Chairperson*)**
All India Cosmetic Manufacturers Association, Gurugram	MS KAJAL ANAND SHRI VIRENDRA V. CHAVAN (*Alternate*)
Cavinkare Private Limited, Chennai	DR T. KUMAR DR GIREESH KUMAR (*Alternate*)
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Consumer Voice, New Delhi	SHRI H. WADHWA
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Food and Drugs Administration, Mumbai	Shri O. S. Sadhwani
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Godrej Consumer Products Limited, Mumbai	Ms Rupinder Kaur Rawat Dr Manoj Gaur (*Alternate*)
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Amendments Issued Since Publication

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